UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,808	12/07/2001	H. William Bosch	029318-0799	8203

7590 05/19/2004

Michele M. Simkin
FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, DC 20007-5143

EXAMINER	
JOYNES, ROBERT M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,808	BOSCH ET AL.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-76 and 93-100* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 77-92* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-76 and 93-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/7/01 & 11/12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' Elections filed on July 17, 2003 and October 8, 2003. Applicants have elected Group I, Claims 14-76 and 93-100 and Species A & G, crystalline active agents and the method of using crystalline active agents, respectively.

Election/Restrictions

Applicant's election with traverse of Group I and Species A & G in Paper filed July 17, 2003 and October 8, 2003 is acknowledged. The traversal is on the ground(s) that the examination of all groups and species. This is not found persuasive because the different groups are distinct form each other in that the methods produce different products (dispersions and emulsions) and the there are different methods of making the stabilized particles as evidenced by the different methods recited in the instant claims. Therefore, the search would be burdensome on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-76 and 93-100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,428,814 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other. U.S. Patent No. 6,428,814 B1 claims a stable bioadhesive nanoparticulate composition comprising an active agent that can be crystalline and a cationic surface stabilizer adsorbed onto the surface of the active agent wherein the effective particle size is less than 4000 nm wherein the particles adsorbs to a biological surface. The instant claims differ in that the independent claims recite the different types of cationic surface stabilizers that can be used. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use a variety of cationic agents as the surface stabilizer. One of ordinary skill in the art would have been motivated to do this to provide different particle that adsorb to various biological surfaces that achieve the same expected results. Therefore, the invention as

a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14, 15, 17-21, 23, 24, 26, 27, 29-32, 34, 36, 37, 39-46, 48, 49-52, 54-59, 61, 62, 64, 66-72, 74, 75, 93 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace et al. (US 6177103 B1). Pace teaches preparing a nanoparticulate composition of less than 2000 nm by adsorbing a cationic agent onto the surface of active agent particles (Col. 4, line 63 – Col. 5, line 21, Col. 5, line 60 – Col. 65, line 5; Col. 6 lines 34-67). Pace does not teach that the nanoparticles can be as large as 4000 nm but do teach anything below 2000 nm is acceptable.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the particles size of active agents to be stabilize by cationic agents.

One of ordinary skill in the art would have been motivated to do this to prepare stable particle of different drugs for different biological site delivery. The drug and target sight will determine how small or large the particles should be for administration of the active with the same expected results.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 22, 28, 35, 47, 53, 60, 65, and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace et al. in combination with Liversidge et al. (US 5145684). The teachings of Pace are discussed above. Pace does not expressly teach that the composition further comprises an excipient or that water is used as the dispersion medium.

Liversidge teaches that such composition can further comprise a carrier (excipient) and that the dispersion medium can be water (Col. 16, Claims 12 and 14).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to add an excipient such as a carrier to such a composition for administration of the composition.

One of ordinary skill in the art would have been motivated to do this to prepare various acceptable dosage forms for the active particles (i.e., injection carriers, oral carriers, or rectal carriers).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 98-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace et al. in combination with Cutie (US 5891420). The teachings of Pace are discussed above. Pace does not expressly teach that the active agent is triamcinolone acetonide.

Cutie teaches that triamcinolone acetonide is a known antiinflammatory (Col. 2, lines 14-25).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use a known antiinflammatory such as triamcinolone acetonide in the composition of Pace.

One of ordinary skill in the art would have been motivated to do this to prepare stable small particles (submicron) of antiinflammatories for proper administration.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Joynes
Patent Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600